IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH and BIOGEN MA INC., Plaintiffs, v. AMNEAL PHARMACEUTICALS INC., et al. Defendants.	**REDACTED PUBLIC VERSION** Civil Action No. 17-cv-823-MN (consolidated)

PROPOSED FINAL PRETRIAL ORDER

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This matter comes before the Court at a final pretrial conference held pursuant to Fed. R. Civ. P. 16 and D. Del. LR 16.3. Plaintiffs Biogen International GmbH and Biogen MA Inc. (collectively "Biogen" or "Plaintiffs") and Defendants (1) Sandoz Inc. ("Sandoz), (2) Prinston Pharmaceutical Inc. ("Prinston"), (3) MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. (collectively "MSN"), (4) Zydus Pharmaceuticals (USA) Inc. ("Zydus"), (5) Aurobindo Pharma U.S.A., Inc. and Aurobindo Pharma USA LLC (collectively "Aurobindo"), (6) Hetero USA Inc., Hetero Labs Limited Unit-III and Hetero Labs Limited (collectively "Hetero"), and (7) Shilpa Medicare Limited ("Shilpa") (collectively "Defendants"), by their undersigned counsel, submit this joint proposed Joint Pretrial Order governing the consolidated bench trial, which is scheduled to begin on December 9, 2019, in Civil Action Nos. 1:17-cv-00824, 1:17-cv-00825, 1:19-cv-00211, 1:17-cv-00845, 1:17-cv-00874, 1:17-cv-00847, and 1:17-cv-00954, which are consolidated in Civil Action No. 1:17-cv-000823-MN (collectively "the Consolidated Actions").

I. Nature of the Consolidated Case

A. Nature of the Actions

1. These are actions for patent infringement of U.S. Patent Nos. 8,399,514 ("the '514 patent")[1] (the "asserted patent") arising under the patent laws of the United States, Title 35, United States Code, §§ 100 *et seq*., including 35 U.S.C. § 271. These actions relate to each Defendant's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, sell, offer to sell, and import generic

[1] The '514 patent is asserted against all Defendants. (*see* C.A. Nos. 1:17-cv-00824, 1:17-cv-00825, 1:17-cv-00845, 1:17-cv-00874, 1:17-cv-00847, and 1:17-cv-00954.)

dimethyl fumarate delayed-release capsules containing 120 mg and 240 mg of dimethyl fumarate ("Defendants' generic products") prior to the expiration of the asserted patent. (C.A. No. 1:17-cv-00824, D.I. 1; C.A. No. 1:17-cv-00825, D.I. 1; C.A. No. 1:19-cv-00211, D.I. 1; C.A. No. 1:17-cv-00845, D.I. 1; C.A. No. 1:17-cv-00874, D.I. 1; C.A. No. 1:17-cv-00847, D.I. 1; and C.A. No. 1:17-cv-00954, D.I. 1 ("the Complaints").)

2. With regard to the '514 patent, the following related actions are currently stayed pending the outcome of this litigation: Accord Healthcare Inc., C.A. No. 1:17-cv-00872, D.I. 163 (D. Del.) (consolidated)[2]; Alkem Laboratories Ltd. and S&B Pharma, Inc., C.A. No. 1:17-cv-00850, D.I. 213 (D. Del.) (consolidated); Amneal Pharmaceuticals LLC, C.A. No. 1:17-cv-00823, D.I. 171 (D. Del.) (consolidated); Cipla Limited and Cipla USA Inc., C.A. No. 1:17-cv-00851, D.I. 223 (D. Del.) (consolidated); Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA, C.A. No. 1:17-cv-00852, D.I. 160 (D. Del.) (consolidated); Graviti Pharmaceuticals Pvt. Ltd. and Graviti Pharmaceuticals Inc., C.A. No. 1:17-cv-00846, D.I. 156 (D. Del.) (consolidated); Lupin Atlantis Holdings SA and Lupin Inc.[3], C.A. No. 1:17-cv-00853, D.I. 143 (D. Del.) (consolidated); Macleods Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc., C.A. No. 1:17-cv-00857, D.I. 214 (D. Del.) (consolidated); Pharmathen S.A., C.A. No. 1:17-cv-00855, D.I. 283 (D. Del.) (consolidated); Slayback Pharma LLC and Slayback Pharma India LLP, C.A. No. 1:17-cv-00828, D.I. 155 (D. Del.) (consolidated); Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc., C.A. No. 1:17-cv-00854, D.I. 169 (D. Del.) (consolidated); TWi Pharmaceuticals, Inc. and TWi Pharmaceuticals USA Inc., C.A. No. 1:17-cv-00856, D.I. 162 (D.

[2] "Consolidated" indicates that the relevant document was filed in the consolidated case, C.A. No. 1:17-cv-00823-LPS (consol.).

[3] Lupin Inc. is dismissed.

Del.) (consolidated); and Windlas Healthcare, Pvt. Ltd., C.A. No. 1:17-cv-00849, D.I. 174 (D. Del.) (consolidated).

3. With regard to the ’514 patent, the following related actions have been dismissed: Accord Healthcare Inc., C.A. No. 1:17-cv-00612, D.I. 10 (M.D.N.C.); Caribe Holdings (Cayman) Co. Ltd. DBA Puracap Caribe and Puracap International LLC, C.A. No. 1:18-cv-00121, D.I. 224 (D. Del.) (consolidated); Impax Laboratories, Inc., C.A. No. 1:17-cv-00826, D.I. 166 (D. Del.) (consolidated); Par Pharmaceutical, Inc., C.A. No. 1:17-cv-00873, D.I. 11 (D. Del.); Par Pharmaceutical, Inc., C.A. No. 1:17-cv-04984, D.I. 13 (S.D.N.Y.); Prinston Pharmaceutical Inc., C.A. No. 1:17-cv-00827, D.I. 172 (D. Del.) (consolidated); Sandoz Inc., C.A. No. 1:17-cv-01606, D.I. 11 (D. Colo.); Stason Pharmaceuticals, Inc. and Sawai Pharmaceutical Co., Ltd., C.A. No. 8:17-cv-01133, D.I. 39 (C.D. Cal.); Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd., C.A. No. 1:17-cv-00875, D.I. 332 (D. Del.) (consolidated); Sun Pharma Global FZE, C.A. No. 1:17-cv-00848, D.I. 239 (D. Del.) (consolidated); Teva Pharmaceuticals USA Inc., C.A. No. 1:17-cv-00829, D.I. 99 (D. Del.) (consolidated); and Zydus Pharmaceuticals (USA) Inc., C.A. No. 3:17-cv-04857, D.I. 8 (D.N.J.).

4. The following defendants have stipulated to infringement of the asserted claims of the ’514 patent: Accord Healthcare Inc., C.A. No. 1:17-cv-00872, D.I. 163 (D. Del.) (consolidated); Alkem Laboratories Ltd. and S&B Pharma, Inc., C.A. No. 1:17-cv-00850, D.I. 213 (D. Del.) (consolidated); Amneal Pharmaceuticals LLC, C.A. No. 1:17-cv-00823, D.I. 171 (D. Del.) (consolidated); Cipla Limited and Cipla USA Inc., C.A. No. 1:17-cv-00851, D.I. 223 (D. Del.) (consolidated); Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA, C.A. No. 1:17-cv-00852, D.I. 160 (D. Del.) (consolidated); Graviti Pharmaceuticals Pvt. Ltd. and Graviti Pharmaceuticals Inc., C.A. No. 1:17-cv-00846, D.I. 156 (D. Del.) (consolidated);

Lupin Atlantis Holdings SA and Lupin Inc.[4], C.A. No. 1:17-cv-00853, D.I. 143 (D. Del.) (consolidated); Macleods Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc., C.A. No. 1:17-cv-00857, D.I. 214 (D. Del.) (consolidated); Pharmathen S.A., C.A. No. 1:17-cv-00855 D.I. 283 (D. Del.) (consolidated); Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd., C.A. 1:17-cv-00875, D.I. 321 (D. Del.) (consolidated); Slayback Pharma LLC and Slayback Pharma India LLP, C.A. No. 1:17-cv-00828, D.I. 155 (D. Del.) (consolidated); Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc., C.A. No. 1:17-cv-00854, D.I. 169 (D. Del.) (consolidated); TWi Pharmaceuticals, Inc. and TWi Pharmaceuticals USA Inc., C.A. No. 1:17-cv-00856, D.I. 162 (D. Del.) (consolidated); Windlas Healthcare, Pvt. Ltd., C.A. No. 1:17-cv-00849, D.I. 174 (D. Del.) (consolidated); Shilpa Medicare Limited (C.A. No. 1:17-cv-00847, D.I. 286 (D. Del.) (consolidated)); Hetero USA Inc., Hetero Labs Limited Unit-III and Hetero Labs Limited, C.A. No. 1:17-cv-00825, D.I. 287 (D. Del.) (consolidated)); Sandoz Inc. and Prinston Pharmaceutical Inc., C.A. No. 1:17-cv-00874, D.I. 319 (D. Del.) (consolidated)); MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc., C.A. 1:17-cv-00845, (D.I. 317 (D. Del. (consolidated); and Zydus Pharmaceuticals (USA) Inc., C.A. No. 1:17-cv-00954, D.I. 326 (D. Del.) (consolidated).

B. Complaints, Asserted Claims and Requested Relief

5. In the Complaints, Plaintiffs have alleged that each defendant will infringe, either literally or under the doctrine of equivalents, the asserted patent under 35 U.S.C. § 271(e)(2) by submitting, or causing to be submitted, to the FDA an ANDA seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration of the asserted patent.

[4] Lupin Inc. is dismissed.

6. Plaintiffs have further alleged that each defendant will induce infringement of and/or contribute to the infringement of the asserted patent if the FDA approves each defendant's respective ANDA and defendants were to sell Defendants' generic products with each defendant's proposed labeling, which is required to copy the FDA approved Tecfidera® labeling.

7. Plaintiffs are asserting the following claims against the Defendants ("the asserted claims"):

Patent	Claims Asserted	Defendants Asserted Against
the '514 patent	1-4, 6, 8-13, 15-16	All Defendants: Aurobindo, Hetero, MSN, Prinston, Sandoz, Shilpa and Zydus

8. In the Complaints, Plaintiffs requested that the Court:

- enter judgment under 35 U.S.C. § 271(e)(2)(A) that each defendant has infringed at least one claim including at least claim 1 of the asserted patent(s) through each Defendant's submission of an ANDA to the FDA seeking to obtain approval to manufacture, use, import, offer to sell and sell Defendants' generic products in the United States before the expiration of the asserted patent(s);
- enter judgment under 35 U.S.C. § 271(b) and/or (c) that each defendant's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' generic products prior to the expiration of the asserted patent(s) constitutes infringement of one or more claims of said patent(s) under 35 U.S.C. § 271(b) and/or (c);
- order that the effective date of any approval by the FDA of Defendants' generic products be a date that is not earlier than the expiration date of the asserted patent(s), or such later date as the Court may determine;

- enjoin each defendant, and all persons acting in concert with each defendant, from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the asserted patent(s), or such later date as the Court may determine;
- declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses and disbursements in this action, including reasonable attorney fees; and
- award such further and other relief as this Court deems proper and just.

C. Defendants' Answers, Defenses, Counterclaims and Requested Relief

1. Aurobindo

9. In its Answer, Defenses and Counterclaims, Aurobindo denied all material allegations asserted by Plaintiffs and asserted the following defenses: (1) non-infringement of the '514 patent, (2) invalidity of the '514 patent, (3) the safe harbor provision of 35 U.S.C. § 271(e)(1), (4) failure to state a claim, (5) costs barred by 35 U.S.C. §288, (6) no willful infringement or exceptional case and (7) reservation of rights to supplement or amend defenses. (C.A. No. 1:17-cv-00824, D.I. 10.) Aurobindo further asserted counterclaims against Biogen seeking declaratory judgments of non-infringement of, invalidity of, and no injunctive remedy for the '514 patent. (*Id.*)

10. Aurobindo requested that the Court enter judgment:

- dismissing the Complaint with prejudice and denying each and every prayer for relief contained therein;
- declaring that Aurobindo's proposed dimethyl fumarate product does not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '514 patent;

- declaring that the ’514 patent is invalid;
- declaring that Biogen is not entitled to any injunctive remedy for the ’514 patent;
- enjoining Biogen and their respective officers, employees, agents, representatives, attorneys and others acting on their behalf, from representing to anyone, either directly or indirectly, that Aurobindo’s proposed dimethyl fumarate product has infringed, are infringing or will infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the ’514 patent;
- awarding Aurobindo its costs;
- declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Aurobindo its attorneys’ fees; and
- awarding to Aurobindo such further relief as this Court may deem necessary, just and proper.

(*Id.*)

2. Hetero

11. In its Answer, Defenses and Counterclaims in C.A. No. 1:17-cv-00825, Hetero asserted the following defenses: (1) non-infringement of the ’514 patent, (2) invalidity and/or unenforceability of the ’514 patent and (3) no exceptional case under 35 U.S.C. § 285. (C.A. No. 1:17-cv-00825, D.I. 13.) Hetero further asserted counterclaims against Biogen seeking declaratory judgments of non-infringement of and invalidity of the ’514 patent. (*Id.*)

12. Hetero requested that the Court enter judgment in its favor and against Biogen, including the following specific relief:

- dismissing the Complaint with prejudice and denying each and every request for relief made therein;

- declaring that claims 1-20 of the ’514 are invalid;
- declaring that the manufacture, use, sale, offer for sale, or importation of the Proposed Product that is the subject of ANDA No. 210500 has not infringed, does not infringe, and would not, if marketing, infringe any valid and enforceable claim of the ’514 patent;
- declaring this case is exceptional and awarding Hetero USA reasonable attorneys’ fees and costs under 35 U.S.C. § 285; and
- awarding Hetero USA such other and further relief as the Court may deem just and proper. (*Id.*)

3. MSN

13. In its Answer, Defenses and Counterclaims, MSN denied all material allegations asserted by Biogen MA Inc. (“Plaintiff”) and asserted the following defenses: (1) non-infringement of the ’514 patent by the filing of MSN’s ANDA No. 210460, (2) non-infringement of the ’514 patent by the manufacture, use, sale, or offer for sale of MSN’s proposed generic products that are the subject of ANDA No. 210460, (3) invalidity of the ’514 patent, (4) failure to state a claim, (5) failure to join a required party, (6) lack of standing, (7) no exceptional case under 35 U.S.C. § 285 and (8) any additional defenses that discovery may reveal. (C.A. No. 1:17-cv-00845, D.I. 12.) MSN further asserted counterclaims against Biogen seeking declaratory judgments of non-infringement of and invalidity of the ’514 patent. (*Id.*)

14. MSN requested that the Court enter a judgment and order in their favor and against Biogen, as follows:

- declaring that MSN has not infringed any valid and enforceable claim of the ’514 patent;

- declaring that the manufacture, use, offer to sell, importation, or sale of MSN's ANDA products would not infringe any valid or enforceable claim of the '514 patent;
- declaring that the claims of the '514 patent are invalid;
- awarding MSN its costs and expenses in this action;
- declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding MSN its attorneys' fees, costs, and expenses in this action; and
- awarding MSN any further and additional relief as the Court deems just and proper.

(*Id.*)

4. Prinston

15. Prinston and Sandoz consented, pursuant to Federal Rule of Civil Procedure 25(c), to the joinder of Prinston as a defendant in the Sandoz Action, C.A. No. 1:17-cv-00874. (C.A. No. 1:17-cv-00823 (consol.), D.I. 180.) All of the claims, counterclaims, and defenses pled by and between Biogen and Sandoz in the Sandoz Action, including those reflected in the complaint, answer, and reply to counterclaims (D.I.s 1, 9, and 13, respectively, in C.A. No. 1:17-cv-00874), shall be deemed to have been pled as well by and between Biogen and Prinston. (*Id.*; *see also infra* Section C.5.)

5. Sandoz

16. In its Answer, Defenses and Counterclaims, Sandoz denied all material allegations asserted by Plaintiffs and asserted the following defenses: (1) non-infringement of the '514 patent by the filing of Sandoz's ANDA No. 210414, (2) non-infringement of the '514 patent by the manufacture, use, sale, or offer for sale of Sandoz's proposed generic products that are the subject of ANDA No. 210414, (3) invalidity of the '514 patent, (4) failure to state a claim, (5) failure to

join a required party, (6) lack of standing, (7) no exceptional case under 35 U.S.C. § 285 and (8) any additional defenses that discovery may reveal. (C.A. No. 1:17-cv-00874, D.I. 9.) Sandoz further asserted counterclaims against Biogen seeking declaratory judgments of non-infringement of and invalidity of the ’514 patent. (*Id.*)

17. Sandoz requested that the Court enter judgment in its favor and against Plaintiffs as follows:

- declaring that Sandoz has not infringed any valid and enforceable claim of the ’514 patent;
- declaring that the manufacture, use, offer to sell, importation, or sale of Sandoz’s ANDA products would not infringe any valid or enforceable claim of the ’514 patent;
- declaring that the claims of the ’514 patent are invalid;
- awarding Sandoz its costs and expenses in this action;
- declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Sandoz its attorneys’ fees, costs, and expenses in this action; and
- awarding Sandoz any further and additional relief as the Court deems just and proper.

(*Id.*)

6. Shilpa

18. In its Answer and Defenses, Shilpa asserted the following defenses: (1) non-infringement of the ’514 patent, (2) invalidity of the ’514 patent and (3) no exceptional case under 35 U.S.C. § 285. (C.A. No. 1:17-cv-00847, D.I. 8.)

7. Zydus

19. In its Answer and Defenses, Zydus asserted the following defenses: (1) non-infringement of the '514 patent, (2) invalidity of the '514 patent and (3) reservation of any and all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation. (C.A. No. 1:17-cv-00954, D.I. 8.)

20. Zydus requested that the Court enter judgment in favor of Zydus dismissing this action with prejudice and awarding Zydus its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper. (*Id.*)

D. Plaintiffs' Answers to Counterclaims and Requested Relief

1. Aurobindo

21. In Plaintiffs' Answer to Aurobindo's counterclaims, Plaintiffs denied all counterclaims asserted by Aurobindo of non-infringement of, invalidity of, and no injunctive remedy for the '514 patent. (C.A. No. 1:17-cv-00824, D.I. 12.)

22. Plaintiffs requested that the Court:

- dismiss Aurobindo's counterclaims with prejudice;
- deny any of the relief Aurobindo seeks in its counterclaims;
- grant Plaintiffs the relief requested in Plaintiffs' Complaint; and
- award Plaintiffs such further and additional relief as this Court deems just and proper.

(*Id.*)

2. Hetero

23. In Plaintiffs' Answer to Hetero's counterclaims, Plaintiffs denied all counterclaims asserted by Hetero of non-infringement of and invalidity of the '514 patent. (C.A. No. 1:17-cv-00825, D.I. 17.)

24. Plaintiffs requested that the Court:

- dismiss Hetero USA's counterclaims with prejudice;
- deny any of the relief Hetero USA seeks in its counterclaims;
- grant Plaintiffs the relief requested in Plaintiffs' Complaint; and
- award Plaintiffs such further and additional relief as this Court deems just and proper.

(*Id.*)

3. MSN

25. In Plaintiff's Answer to MSN's counterclaims, Plaintiff denied all counterclaims asserted by MSN of non-infringement of and invalidity of the '514 patent. (C.A. No. 1:17-cv-00845, D.I. 15.)

26. Plaintiff requested that the Court:

- dismiss MSN's counterclaims with prejudice;
- deny any of the relief MSN seeks in its counterclaims;
- grant Plaintiff the relief it requested in Plaintiff's Complaint; and
- award Plaintiff such further and additional relief as this Court deems just and proper.

(*Id.*)

4. Prinston

27. Prinston and Sandoz consented, pursuant to Federal Rule of Civil Procedure 25(c), to the joinder of Prinston as a defendant in the Sandoz Action, C.A. No. 1:17-cv-00874. (C.A. No. 1:17-cv-00823 (consol.), D.I. 180.) All of the claims, counterclaims, and defenses pled by and between Biogen and Sandoz in the Sandoz Action, including those reflected in the complaint, answer, and reply to counterclaims (D.I.s 1, 9, and 13, respectively, in C.A. No. 1:17-cv-00874), shall be deemed to have been pled as well by and between Biogen and Prinston. (*Id.*; *see also infra* Section C.5.)

5. Sandoz

28. In Plaintiffs' Answer to Sandoz's counterclaims, Plaintiffs denied all counterclaims asserted by Sandoz of non-infringement of and invalidity of the '514 patent. (C.A. No. 1:17-cv-00874, D.I. 13.)

29. Plaintiffs requested that the Court:

- dismiss Sandoz's counterclaims with prejudice;
- deny any of the relief Sandoz seeks in its counterclaims;
- grant Plaintiffs the relief requested in Plaintiffs' Complaint; and
- award Plaintiffs such further and additional relief as this Court deems just and proper.

(*Id.*)

6. Shilpa

30. Shilpa did not assert any counterclaims against Plaintiff. (C.A. No. 1:17-cv-00847, D.I. 8.)

7. Zydus

31. Zydus did not assert any counterclaims against Plaintiffs. (C.A. No. 1:17-cv-00954, D.I. 8.)

E. Consolidation

32. On February 2, 2018, the Court consolidated C.A. Nos 1:17-cv-00824, 1:17-cv-00825, 1:17-cv-00845, 1:17-cv-00874, 1:17-cv-00847, 1:17-cv-00875, and 1:17-cv-00954 under the lead case, *Biogen International GmbH, et al. v. Amneal Pharmaceuticals LLC, et al.*, C.A. No. 1:17-cv-00823-LPS (D.I. 22.) On March 1, 2019, the Court consolidated C.A. No. 1:19-cv-00211 under the same lead case. An order staying the action against Amneal Pharmaceuticals LLC was entered on September 11, 2018. (C.A. No. 1:17-cv-00823-LPS (consolidated), D.I. 171.) On November 13, 2019, the consolidated action was reassigned to Judge Maryellen Noreika (C.A. No. 1:17-cv-00823-MN (consolidated), *see* D.I. 329.).

F. Claim Construction

33. On October 2, 2018, Plaintiffs and certain Defendants, including Aurobindo, Hetero, MSN, Prinston, Sandoz, Sawai, Shilpa and Zydus, filed a joint claim statement stipulating to the construction of certain terms of the asserted patent. The parties stipulated to construction of the ’514 patent claim term “a pharmaceutical composition consisting essentially of . . . a therapeutically effective amount of dimethyl fumarate . . . wherein the therapeutically effective amount of dimethyl fumarate . . . is about 480 mg per day” in the ’514 patent claims 1 and 15 as “[t]his phase[sic] has its plain and ordinary meaning, which includes that the pharmaceutical composition is therapeutically effective for treating multiple sclerosis.” (D.I. 185.)

G. Prior Motions

34. There are no prior motions.

H. Pending Motions

35. There are no pending motions.

II. Jurisdiction

36. This is a consolidated action for patent infringement of U.S. Patent Nos. 8,399,514 ("the '514 patent")[5] arising under the patent laws of the United States, Title 35, United States Code, §§ 100 *et seq*., including 35 U.S.C. § 271.

37. Personal jurisdiction is not disputed for purposes of this action and is based on the reasons stated in each Complaint[6] and each Defendant's corresponding answer.[7] Subject matter jurisdiction is not disputed for purposes of this action and is based on 28 U.S.C. §§ 1331 and 1338(a). (*See* Defendants' Jurisdiction Answers.[8])

38. Venue is not disputed for the purposes of this action and is based on 28 U.S.C. §§ 1391(b) and (c) and § 1400(b) for the entities incorporated in Delaware and on the answers of those Defendants not incorporated in Delaware that state that the defendant does not contest venue in this action. (*Id.*)

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[5] The '514 patent is asserted against all Defendants. (*see* C.A. Nos. 1:17-cv-00824, 1:17-cv-00825, 1:17-cv-00845, 1:17-cv-00874, 1:17-cv-00847, 1:17-cv-00875, and 1:17-cv-00954.)

[6] Aurobindo Complaint, C.A. No. 1:17-cv-00824, D.I. 1 at ¶¶ 9-24; Hetero Complaint, C.A. No. 1:17-cv-00825, D.I. 1 at ¶¶ 14-33; MSN Complaint, C.A. No. 1:17-cv-00845, D.I. 1 at ¶¶ 10-29; Sandoz Complaint, C.A. No. 1:17-cv-00874, D.I. 1 at ¶¶ 7-16; Stipulated Order Joining Prinston, C.A. No. 1:17-cv-00874, D.I. 22 at ¶ 8; Shilpa Complaint, C.A. No. 1:17-cv-00847, D.I. 1 at ¶¶ 6-16; and Zydus Complaint, C.A. No. 1:17-cv-00954, D.I. 1 at ¶¶ 7-16.

[7] Aurobindo Answer, C.A. No. 1:17-cv-00824, D.I. 10 at ¶¶ 9-24; Hetero Answer, C.A. No. 1:17-cv-00825, D.I. 13 at ¶¶ 14-33 MSN Answer, C.A. No. 1:17-cv-00845, D.I. 12 at ¶¶ 10-29; Sandoz Answer, C.A. No. 1:17-cv-00874, D.I. 9 at ¶¶ 7-16; Stipulated Order Joining Prinston, C.A. No. 1:17-cv-00874, D.I. 22 at ¶ 8; Shilpa Answer, C.A. No. 1:17-cv-00847, D.I. 8 at ¶¶ 6-16; and Zydus Answer, C.A. No. 1:17-cv-00954, D.I. 8 at ¶¶ 7-16.

[8] *Id.*

III. Facts

A. Uncontested Facts

39. The parties' Joint Statement of Uncontested Facts with regard to validity is attached as **Exhibit 1**. The facts are not disputed or have been agreed to or stipulated to by the parties. These facts should become part of the evidentiary record in this consolidated action.

40. Any party, with prior notice to all other parties, may read any or all of the uncontested facts to the jury or Court, and will be charged for the time used to do so.

B. Contested Facts

41. Plaintiffs' statement of Contested Facts to be Litigated with regard to validity are attached as **Exhibit 2**.

42. Defendants' statement of Contested Facts to be Litigated with regard to validity are attached as **Exhibit 3**.

43. Plaintiffs' statement of Contested Facts to be Litigated with regard to infringement are attached as **Exhibit A1**.

44. If this Court determines that any issue identified in the statements of Contested Facts to be Litigated is more properly considered an issue of law, it should be so considered.

IV. Issues of Law

45. Plaintiffs' statement of Issues of Law to be Litigated is attached as **Exhibit 4**.

46. Defendants' statement of Issues of Law to be Litigated is attached as **Exhibit 5**.

47. If this Court determines that any issue identified in the statements of Issues of Law to be Litigated is more properly considered an issue of fact, it should be so considered.

V. Witnesses

48. Presentation of evidence will follow the burden of proof.

49. In the absence of an alternative agreement between the parties, fact witnesses will be sequestered.

50. Unless otherwise agreed between the parties, the parties will identify witnesses expected to testify **by 7:00 p.m. two calendar days before the direct examination** will take place. The other party shall identify any objections to such witness(es) **by 8:30 p.m. the following day** and the parties shall meet and confer to resolve any objections **by 9:30 p.m. that same evening**. If good faith efforts to resolve the objections fail, the party objecting shall bring its objections to the Court's attention prior to the witness being called to the witness stand.

51. The parties shall exchange a final list of witnesses they intend to call live at trial two (2) weeks in advance of the trial date. A party shall promptly provide notice if it will not call live a witness who is so identified on the list of trial witnesses. To the extent a party gives notice that a witness identified as a live witness on the list of trial witnesses is not going to be called live, the parties may provide designations and counter-designations of the witness's deposition transcript, as well as objections to the opposing party's designations, in a reasonable time frame as agreed upon between the parties.

52. The parties will **confer nightly** to update opposing counsel as to the expected day that the party intends to complete its presentation of evidence.

53. The parties' witness lists, see Section V.A and Section V.B below, are a good faith representation of the witnesses currently expected to testify at trial, not a commitment that any of the witnesses listed will appear to testify live at trial. To the extent that a witness's circumstances change, or a witness otherwise becomes unavailable for trial, the parties agree to timely notify the other parties and supplement their witness list. In the event a fact witness either of the parties have

identified as testifying live at trial becomes unavailable, each party reserves the right to call that witness by deposition, as set forth below in this pretrial order.

54. The parties further reserve the right to call: (1) one or more additional witnesses whose testimony is necessary to establish authenticity or admissibility of any trial exhibit, if that evidentiary status of the exhibit is challenged by an opposing party the parties will work together in good faith to resolve authentication and admissibility issues without the need for live testimony, if possible); (2) additional witnesses to respond to any issues raised by the Court's pretrial or trial rulings; (3) any witness live for impeachment purposes to the extent permitted by applicable rules; and (4) any witness who appears on the other party's witness list.

55. Any witness not listed in the parties' witness lists, see Section V.A. and Section V.B below, or provided for in the preceding paragraph above will be precluded from testifying absent good cause shown.

A. List of Witnesses Plaintiffs Expects to Call

56. Plaintiffs' List of Witnesses to be Called Live or By Deposition with regard to validity is attached as **Exhibit 6,** and it includes both expert and non-expert witnesses and any objections to a witness by Defendants with a brief statement of the basis for the objection. Plaintiffs' List of Witnesses to be Called Live or By Deposition with regard to infringement is attached as **Exhibit A2,** and it includes both expert and non-expert witnesses and any objections to a witness by Defendants with a brief statement of the basis for the objection.

57. For any expert witness, Exhibit 6 and Exhibit A2 identifies the subject matter on which Plaintiffs will ask the Court to recognize the witness's expertise. No deviations as to the described subject matter will be permitted without approval of all parties or the Court, on good cause shown.

B. List of Witnesses Defendants Expects to Call

58. Defendants' List of Witnesses to be Called Live or By Deposition with regard to the '514 patent is attached as **Exhibit 7** and it includes both expert and non-expert witnesses and any objections to a witness by Plaintiffs with a brief statement of the basis for the objection.

59. For any expert witness, Exhibit 7 identifies the subject matter on which Defendants will ask the Court to recognize the witness's expertise. No deviations as to the described subject matter will be permitted without approval of all parties or the Court, on good cause shown

C. List of Witnesses Third Parties Expect to Call

60. There are no third parties to the action.

D. Testimony by Deposition

61. A key to the objection codes used by both Plaintiffs' and Defendants' for objections to deposition testimony is attached as **Exhibit 8** and **Exhibit 9**, respectively.

62. Plaintiffs identify the deposition testimony that Plaintiffs may offer into evidence with regard to validity in **Exhibit 10**. Plaintiffs' deposition designations, Defendants' objections to the designations, Defendants' counter designations, and Plaintiffs' objections to the counter designations are listed in Exhibit 10. Plaintiffs and Aurobindo have agreed to identify deposition testimony that may be offered into evidence with regard to infringement, and any objections or counter designations, at a later date prior to trial.

63. Defendants identify the deposition testimony that Defendants may offer into evidence in **Exhibit 11.** Defendants' deposition designations, Plaintiffs' objections to the designations, Plaintiffs' counter designations, and Defendants' objections to the counter designations are listed in Exhibit 11.

64. With respect to those witnesses whom the parties have identified in Exhibits A2, 6 and 7 that will be called to testify live at trial, no deposition designations or counter-designations

are required. Should a fact witness identified in Exhibits A2, 6 and 7 as testifying live at trial become unavailable, as that term is defined in the Federal Rules of Civil Procedure and Federal Rules of Evidence, the parties are permitted to designate specific pages and lines of deposition testimony that they intend to read or play in lieu of the witness's appearance upon reasonable notice. The parties shall only identify those witnesses they intend to call to testify live at trial that they believe in good faith they will call to testify live at trial, and the parties shall immediately notify each other in the event they have decided not to call a witness to testify live at trial.

65. Subject to the preceding paragraph, this pretrial order contains the maximum universe of deposition designations, counter-designations, and objections to admission of deposition testimony; none of the foregoing shall be supplemented without approval of all parties or leave of the Court, on good cause shown. A party's decision not to introduce some or all of the testimony of a witness designated by that party herein shall not be commented upon by the other party at trial. Either party is entitled to use the deposition testimony as designated herein by the other party.

66. For deposition testimony provided to the Court, the parties providing the designated testimony shall serve the other parties with the transcript pages and line numbers of the deposition testimony they intend to introduce **by 7:00 p.m. four calendar days before** such testimony is to be introduced, and identify the manner in which the deposition will be used, either by video or reading the transcript into the record. The opposing parties will identify any objections to the designated deposition testimony and any specific pages and lines from that deposition to counter-designate **by 7:00 p.m. two calendar days before** such testimony is to be introduced), Anticipated objections are listed in Exhibits 10 and 11, and the parties shall not be permitted to add or assert different objections to deposition testimony designated or counter-designated in Exhibits 10 and

11. By **8:00 pm one calendar day before such testimony is to be introduced**, the introducing party will identify any objections to the other party's counter-designated testimony. The parties shall meet and confer to resolve any objections to designated testimony **by 10:00 p.m. that same day** (one calendar day before such testimony is to be introduced).

67. If there are objections that remain to be resolved, the party calling the witness by deposition shall, no later than one (1) calendar days before the witness is to be called at trial, submit, on behalf of all parties: (i) a copy of the entire deposition testimony of the witness at issue, clearly highlighting the designations, counter-designations, and pending objections; and (ii) a cover letter clearly identifying the pending objections as well as a brief indication (i.e., no more than one sentence per objection) of the basis for the objection and the offering party's response to it. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of the deposition testimony or waiver of objection to the use of the deposition testimony.

68. All irrelevant and redundant material, including colloquy between counsel and objections, will be eliminated when the deposition is read or viewed at trial.

69. When the witness is called to testify by deposition at trial, the party calling the witness shall provide the Court with two copies of the transcript of the designations and counter-designations that will be read or played. In the case of designations played via video, the parties will be charged for elapsed time that corresponds to the video length of the lines of testimony the party designated. If the designations are read, the parties will be charged for the time that corresponds to the lines of testimony the party designated.

70. When deposition designation excerpts are introduced, all admissible deposition counter-designation excerpts will be introduced simultaneously in the sequence in which the

testimony was originally given. The specific portions of the deposition shall be read or played in page order. If an exhibit is referenced in a deposition designation, the exhibit is admitted into evidence if it is included on the offering party's trial exhibit list, is not otherwise objected to, and the offering party formally moves the exhibit into evidence by exhibit number.

E. Impeachment with Prior Inconsistent Testimony

71. Pursuant to Fed. R. Evid. 613, deposition and other testimony or statements not specifically identified on a party's deposition designation list or exhibit list may be used at trial only for the purpose of impeachment, if otherwise competent for such purpose. The Court will rule at trial on any objections based on lack of completeness and/or lack of consistency.

F. Objections to Expert Testimony

72. The parties request that the Court rule at trial on any objections to expert testimony beyond the scope of expert disclosures. In the event of any such objection, the parties shall provide copies of that expert's report(s) and deposition testimony to the Court. However, unless expressly moved and accepted into evidence, the expert report(s) and deposition testimony shall be used only for the purpose of ruling on objections to expert testimony offered at trial.

VI. Exhibits

A. Exhibits

73. A Key to the objection codes used by both Plaintiffs' and Defendants' for objections to exhibits is attached as **Exhibit 12** and **Exhibit 13**, respectively.

74. Plaintiffs' list of exhibits that they may offer at trial, except demonstrative exhibits and exhibits to be used solely for impeachment, and Defendants' objections to Plaintiffs' exhibits, are attached as **Exhibit 14**. Plaintiffs' trial exhibits will be identified with PTX numbers, starting at PTX 1. Plaintiffs' demonstratives will be identified with PDX numbers. Plaintiffs and

Aurobindo have agreed to identify exhibits that may be offered at trial with regard to infringement, and any objections, at a later date prior to trial.

75. Defendants' joint list of exhibits that they may offer at trial, except demonstrative exhibits and exhibits to be used solely for impeachment, and Plaintiffs' objections to Defendants' exhibits, are attached as **Exhibit 15**. Defendants' trial exhibits will be identified with DTX numbers, starting at DTX 1. Defendants' demonstratives will be identified with DDX numbers.

76. The parties agree that exhibits to be used solely for impeachment and/or cross-examination need not be included on the lists of trial exhibits or disclosed in advance of being used at trial.

77. This pretrial order contains the maximum universe of exhibits to be used in any party's case-in-chief, as well as all objections to the admission of such objections, neither of which shall be supplemented without approval of all parties or leave of the Court, on good cause shown. Exhibits not listed will not be admitted unless good cause is shown.

78. No exhibit will be admitted unless offered into evidence through a witness, who must at least be shown the exhibit. At some point before the completion of the trial, any party that has used an exhibit with a witness and wishes that exhibit to be admitted into evidence must formally move the exhibit into evidence, by exhibit number. This applies to exhibits offered through live testimony and designated testimony.

79. A party will provide a list of the exhibits to be used in connection with live direct examination **by 7:00 p.m. the night before** their intended use, and objections will be provided **no later than 8:30 p.m. the night before** their intended use. The parties shall meet and confer **by 9:30 p.m. the night before** their intended use in order to attempt to resolve any objections. If good faith efforts to resolve the objections fail, the parties defer to the Court for ruling on

objections either prior to the witness being called to the witness stand or during the witness's testimony. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of an exhibit or waiver of objection to the exhibit.

80. Exhibits not objected to will be received into evidence by the operation of the Final Pretrial Order without the need for additional foundation testimony, provided they are shown to a witness. Nothing herein shall be construed as a stipulation or admission that the document is entitled to any weight in deciding the merits of this case. The parties agree that any description of a document on an exhibit list is provided for convenience only and shall not be used as an admission or otherwise as evidence regarding the listed document or any other listed document.

81. Any party may use an exhibit that is listed on the other party's exhibit list, to the same effect as though it were listed on its own exhibit list, subject to all evidentiary objections. Any exhibit, once admitted, may be used equally by each party, subject to any limitations as to its admission. The listing of a document on a party's exhibit list is not an admission that such document is relevant, or admissible, when offered by the opposing side for the purpose that the opposing side wishes to admit the document. Each party reserves the right to object to the relevance of any evidence offered by the other party, at the time such evidence is offered, in view of the specific context in which such evidence is offered.

82. Legible copies of United States patents, file histories, and the contents of United States and foreign patents and translations thereof (if in English or translated into English) may be offered and received in evidence in lieu of certified copies thereof, subject to all other objections which might be made to the admissibility of certified copies.

83. On or before the first day of trial, counsel will deliver to the Courtroom Deputy a completed AO Form 187 exhibit list for each party.

B. Demonstrative Exhibits

84. The parties agree that the demonstrative exhibits that the parties intend to use at trial do not need to be included on their respective exhibit lists that are part of this Final Pretrial Order. Plaintiffs' demonstrative exhibits will be identified with PDX numbers. Defendants' demonstrative exhibits will be identified with DDX numbers.

85. The parties will exchange demonstratives to be used in opening statements **by 12:00 p.m. noon the day before opening statements**. The parties will provide any objections to such demonstratives **by 6:00 p.m. on the night before opening statements**. The parties shall meet and confer **by 8:00 p.m. the night before opening statements.**

86. A party will provide demonstrative exhibits to be used in connection with direct examination **by 7:00 p.m. the night before** their intended use, and objections will be provided no later than **8:30 p.m. the night before** their intended use. The parties shall meet and confer **by 9:30 p.m. the night before** their intended use. If any of the demonstratives change after the deadline, the party intending to use the demonstrative will promptly notify the opposing party of the change(s).

87. The party seeking to use a demonstrative will provide a color representation of the demonstrative to the other side in PDF form. However, for video or animations, the party seeking to use the demonstrative will provide it to the other side on a DVD or CD. For irregularly sized physical exhibits, the party seeking to use the demonstrative will provide a color representation as a PDF of 8.5 x 11 copies of the exhibits.

88. These provisions do not apply to demonstratives intended for use in closing statements, created during testimony or demonstratives to be used for cross-examination, none of

which need to be provided to the other side in advance of their use. In addition, blow-ups or highlights of exhibits or parts of exhibits or testimony are not required to be provided to the other side in advance of their use.

89. If good faith efforts to resolve objections to demonstrative exhibits fail, the objecting party shall bring its objections to the Court's attention prior to the opening statements or prior to the applicable witness being called to the witness stand. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of an exhibit or waiver of objection to the exhibit.

VII. Damages

90. As of November 16, 2019, Plaintiffs are not claiming damages. If any Defendant launches its proposed generic dimethyl fumarate products prior to the Court's decision in this consolidated action, the parties will inform the Court promptly.

VIII. Bifurcated Trial

91. The parties do not request a bifurcated trial.

IX. Motions *in Limine*

A. Plaintiffs' Motions *in Limine*

1. Motion *in Limine* (No. 1) to Preclude Defendants' Experts from Offering Testimony Related to Biogen's Intent, Motive or State of Mind

92. Plaintiffs' Opening Motion is attached at **Exhibit 16**. Defendants' Opposition to the Motion is attached at **Exhibit 17**. Plaintiffs' Reply to the Opposition is attached at **Exhibit 18**.

2. Motion *in Limine* (No. 2) to Exclude Evidence and Arguments Related to Derivation or Invention by FDA

93. Plaintiffs' Opening Motion is attached at **Exhibit 19**. Defendants' Opposition to the Motion is attached at **Exhibit 20**. Plaintiffs' Reply to the Opposition is attached at **Exhibit 21**.

3. Motion *in Limine* (No. 3) to Exclude Evidence Related to Using the O'Neill Presentation as Prior Art

94. Plaintiffs' Opening Motion is attached at **Exhibit 22**. Defendants' Opposition to the Motion is attached at **Exhibit 23**. Plaintiffs' Reply to the Opposition is attached at **Exhibit 24**.

B. Defendants' Motions *in Limine*

95. Defendants are not submitting any motions *in limine*.

X. Discovery

96. Discovery is completed.

XI. Number of Jurors

97. This is a non-jury trial.

XII. Non-Jury Trial

98. The parties request a detailed opinion from the Court post-trial.

99. Along with their opening post-trial briefs, each party shall provide proposed Findings of Fact, separately stated in numbered paragraphs, constituting a detailed listing of the relevant material facts the party believes it has proven, in a simple narrative form, along with citations to the record. No separate Conclusions of Law shall be filed.

100. The parties propose the following page limits:

a. The proposed Findings of Fact shall be limited to a maximum of 100 pages.

b. The opening post-trial briefs shall be limited to a maximum of 35 pages.

c. The responsive post-trial briefs shall be limited to 20 pages.

101. The parties propose the following post-trial briefing schedule:

a. The parties simultaneously exchange their opening post-trial briefs, along with proposed Findings of Fact, on Friday, January 31, 2020.

b. The parties simultaneously exchange their responsive post-trial briefs on Friday, February 28, 2020.

XIII. Length of Trial

102. This matter is currently scheduled for a **5-day** bench trial beginning with opening statements at **12:00 p.m.** on **December 6, 2019.** The remainder of trial is currently scheduled to take place on December 9, 2019 and December 11, 2019 through December 13, 2019, each day beginning at 8:30 a.m. (D.I. 334.) The trial day is currently scheduled to end at 6:00 p.m. each day. (*Id.*)

103. The order of presentation of evidence and argument will be as follows:

a. Opening statements

b. Defendants' case-in-chief on issues of invalidity

c. Plaintiffs' rebuttal case on issues of invalidity

d. Defendants' reply case on issues of invalidity

e. Closing arguments

104. The trial will be timed. Unless otherwise ordered, time will be charged to a party for its opening statement, direct and redirect examinations of witnesses it calls, cross-examination of witnesses called by any other party, closing argument, its argument on any motions for judgment as a matter of law, and all sides' argument on objections a party raises (outside the presence of the jury) to another party's exhibits and demonstrative exhibits.

105. The Courtroom Deputy will keep a running total of trial time used by counsel. If any party uses all of its allotted trial time, the Court will terminate that party's trial presentation.

XIV. Motions for Judgment as a Matter of Law

106. The parties have agreed to the following procedure: The parties reserve the right to move pursuant to Fed. R. Civ. P. 52(c) for judgment on partial findings. The parties agree that either party making a motion pursuant to Fed. R. Civ. P. 52(c) will advise the Court of its motion promptly and in accordance fully with Fed. R. Civ. P. 52(c). If the Court requests more extensive argument on the motion, such argument will be taken up at the Court's first convenience. Supplementation of the motion in writing shall be made only upon request by the Court. Pursuant to Fed. R. Civ. P. 52(c), the Court may decline to render any judgment until the close of evidence.

XV. Amendments of the Pleadings

107. No amendments to the pleadings are sought by the parties at this time.

XVI. Additional Matters

108. **Plaintiffs' Statement.** Plaintiffs' anticipate requesting that the courtroom be closed to the public for a portion of the testimony related to Biogen's highly confidential internal business documents.

109. **Defendants' Statement.** Defendants disagree with Plaintiffs' request to close the courtroom to the public for a portion of the trial. Plaintiffs have not identified with particularity the information that it seeks to withhold from public access or the specific injury that Plaintiffs expect from public disclosure in court.

110. In light of the Court's Oral Order (D.I. 334) setting the trial schedule, Defendants request that the Court permit Defendants' expert, Dr. Wee Yong, to testify on December 6th after the parties' opening statements. Although Dr. Yong has professional commitments during the weeks of December 2nd and December 9th, Dr. Yong can more easily revise his plans to be able to

testify on December 6th. In particular, Dr. Yong is hosting as co-chair a national conference on multiple sclerosis in Calgary, Canada that impacts his availability to testify the week of December 9th.

XVII. Settlement

111. The parties certify that they have engaged in a good faith effort to explore the resolution of the controversy by settlement and that no agreement has been reached. As of the filing date of this order, the parties are continuing to discuss settlement, but still intend to proceed to trial.

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IT IS HEREBY ORDERED that this Final Pretrial Order shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice.

DATED: _____

_____
UNITED STATES DISTRICT JUDGE